[Translation of the claims as published along with the International application]

CLAIMS

1. Fragment of nucleic acids specific mycobacteria belonging to the *M. tuberculosis* complex, comprising a sequence of nucleotides selected from the sequence SEQ ID No. 1, the sequence SEQ ID No. 2, their complementary sequences or the sequences of nucleic acids capable of hybridizing with one of the preceding sequences under conditions of high stringency.

2. Fragment of nucleic acids specific to the *M. tuberculosis* complex, comprising a sequence of nucleotides selected from the sequence SEQ ID No. 1, its complementary sequence or the sequences of nucleic acids capable of hybridizing with one of the preceding sequences under conditions of high stringency.

3. Fragment of nucleic acids specific to members of the *M. tuberculosis* complex which are different from BCG, comprising a sequence of nucleotides selected from the sequence SEQ ID No. 2, its complementary sequence or the sequences of nucleic acids capable of hybridizing with one of the preceding sequences under conditions of high stringency.

4. Cloning and/or expression vector containing a sequence of nucleic acids according to Claim 1.

5. Vector according to Claim 4, characterized in that it is the plasmid pRegX3Bcl or PRegX3Mtl respectively deposited at the CNCM under the numbers I-1765 and I 1766.

6. Nucleotide probe or nucleotide primer characterized in that it hybridizes specifically with any one of the sequences according to Claim 1, the corresponding RNA sequences or the corresponding genes.

7. Nucleotide probe according to Claim 6, comprising 24 consecutive nucleotides selected from the sequences of nucleic acids according to Claim 1.

8. Nucleotide probe according to Claim 5, characterized in that it comprises the sequence SEQ ID No. 1 or its complementary strand.

9. Nucleotide probe according to Claim 6, characterized in that it comprises two successive sequences SEQ ID No. 1, followed by a sequence SEQ ID No. 2.

10. Nucleotide probe for the detection of specific sequences of nucleic acids of members of the *M. tuberculosis* complex which are different from BCG, characterized in that it is a sequence corresponding to the region of the sequence SEQ ID No. 2 surrounding the GAG codon in the positions 40 to 42 or of its complementary strand.

11. Nucleotide probe according to Claim 10, characterized in that it is a sequence composed of 9 base pairs upstream and 9 base pairs downstream of the GAG codon in the specific positions 40 to 42 of the sequence SEQ ID No. 2.

12. Nucleotide probe according to Claim 10, characterized in that it is the sequence SEQ ID No. 2 or its complementary strand.

13. Nucleotide probe according to Claim 6, characterized in that it is labelled by dioxygenin.

14. Nucleotide primers for the amplification of a specific nucleotide sequence of mycobacteria belonging to the *M. tuberculosis* complex, comprising nucleotide sequences corresponding to the sequences adjacent to the senX3-regX3 intergenic region, in the regions 3' of senX3 and 5' of regX3.

15. Primers according to Claim 14, characterized in that they comprise 19 nucleotides.

16. Primers according to Claim 14, characterized in that they are the pair of primers 5'GCGCGAGAGCCCGAACTGC3' (Seq. ID NO:4) and 5'GCGCAGCACAAACCTCAGC3' (Seq. ID NO:5).

17. Use of a sequence according to Claim 1, for the production of diagnostic nucleotide probes or of

nucleotide primers which can be used in an enzymatic amplification method.

18. Use of a probe according to any one of Claims 6 to 13 as an in vitro tool for detection or for diagnosis of strains of mycobacteria belonging to the *M. tuberculosis* complex.

19. Method of detection of strains of mycobacteria belonging to the *M. tuberculosis* complex in a biological sample, comprising the following steps:

(i) contacting the biological sample with a pair of primers according to any one of Claims 6, 14 to 16 under conditions allowing hybridization of the said primers to the specific nucleic acids of strains of mycobacteria belonging to the *M. tuberculosis* complex;

(ii) amplification of the said nucleic acids;

(iii) contacting a nucleotide probe according to any one of Claims 6 to 13 with the said biological sample under conditions allowing the formation of hybridization complexes between the said probe and the amplified sequences of nucleic acids;

(iv) detection of the hybridization complexes formed.

20. Method according to Claim 19, characterized in that step (iii) is carried out with a nucleotide probe according to Claim 8.

21. Method of detection of the presence of members of the *M. tuberculosis* complex other than BCG in a biological sample according to Claim 19, characterized in that step (iii) is carried out with a nucleotide probe according to Claim 10.

22. Method of detection and of differential diagnosis of BCG and of other members of the *M. tuberculosis* complex in a biological sample, characterized in that a detection method according to Claim 20 is carried out and in a search is made among the amplified nucleic acids capable of forming hybridization complexes those are found which are

likewise capable of forming hybridization complexes with a nucleotide probe according to Claim 10.

24. Method according to Claim 21 or Claim 22 for differentiating an infection by BCG from an infection by a virulent mycobacterium of the *M. tuberculosis* complex in an immunodeficient subject.

24. Method according to Claim 23, characterized in that the immunodeficient subject is a subject infected with HIV.

25. Method for the identification of groups of mycobacteria belonging to the *M. tuberculosis* complex, characterized in that:

- the DNA of the said strains previously extracted with a pair of primers according to any one of Claims 6, 14 to 16 is contacted under conditions allowing a specific hybridization of the primers with one of the sequences according to Claim 1 and the obtainment of amplification products, and

- the length of the amplification products obtained is measured.

26. Method according to Claim 25, characterized in that the pair of primers according to Claim 16 is used.

27. Kit for the <u>in vitro</u> identification of strains of mycobacteria belonging to the *M. tuberculosis* complex in a biological sample comprising:

- a pair of primers according to any one of Claims 6, 14 to 16;

the reagents necessary to allow the amplification of the sequences of nucleic acids.

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